

MediSet®, sterile

Pince anatomique, 7120562

Intended Purpose

Intended Use:

The small surgery sets are single-use, sterile sets made with various components, intended to perform a small surgery in or out the OP room.

During a small surgery procedure, such operations can be done:

- placement of an IUD (intrauterine device)
- realization of a skin biopsy
- placing/removal of a subcutaneous implant, circumcision

The care is performed by a healthcare professional on all kinds of patient without restriction on age or gender.

The small surgery set is generally used less than 60 minutes but it might be possible that the use duration is longer. There is no accumulated use of the care set.

The components might be in contact with skin, mucosal membranes, injured skin, blood for a short-term use.

Target user/group: Healthcare professionals

Medical device class of the set (based on component with the highest classification): Is

“The MediSet is a procedure pack.”

Application/Indication

The indication results from the necessity to perform a small surgery in or out the OP room.

That could include:

- Realization of an IUD (intrauterine device)
- Realization of a skin biopsy
- Placing/removal of a subcutaneous implant
- Circumcision

Reference Number

7120562

Quantity	Component description	Included substances
1	Forceps anatomic atraumatic straight 12,5 cm	See set label

Instruction for use, Contra-Indications and Undesirable Side Effects, Warnings:



Consult instructions for use



Caution

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For possible contraindications please follow the instructions/warning hints of the individual set items listed in the instructions for use enclosed within the set.

Sterile Device:



Sterilized using ethylene oxide



Do not use if package is damaged



Do not re-sterilize

Single Use Device:



Do not re-use

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

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Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of MediSet® should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the kitpacker.

Product Performance Characteristics

Property	Applicable standard
Manufacturing practice in cleanroom conditions	FDA Guide on sterile Drug Products EN ISO 14644
Packaging	DIN EN ISO 11607
Sterilization	DIN EN ISO 11135-1
Transport	DIN EN ISO 11607, ISO/TS 16775, ASTM D4169, ISTA Test procedures 2A, 3A & 3B
Biological evaluation	DIN EN ISO 10993
Risk management	EN ISO 14971
Symbols medical devices	EN ISO 15223-1
Quality Management System	EN ISO 13485

Labelling

For complete Set labeling see set label.

The set is offered with a repositionable sticker showing barcode for the traceability. It can be stuck on patients file.

Data matrix according to GS1: EAN-128 codes readable on each packaging level.

Lot-No. with 8-Digit Code

e.g.:



0

12

XXXXX

year

week of
production

for internal purposes only

Manufacturing Date

e.g.:



2015
year

04
month

07
day

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Use-by-Date

e.g.:  2015 04 07
year month day

Shelf Life: Maximum 3 years, or the shelf life of the component with the shortest shelf-life

Medical Devices in the set are indicated by following symbol



Unique Device Identification (UDI) for the set:



Single Sterile Barrier System



Single sterile barrier system

Packaging: Multivac in Hard Blister in 1 Alveolas

Primary packaging/transport carton	Primary packaging/dispenser	transport carton/pallet	Primary packaging dimension	Dispenser dimension	Transport carton dimension	Pallet dimension
100	n.a.	110	175 x 70 x 20 mm	n.a	340 x 230 x 140 mm	1200 x 800 x 1928 mm

Latest Date of Revision: 2021-04-20